

III. REMARKS

This document is being submitted in response to the non-final Office Action mailed by the Patent Office on February 23, 2007. In the present application, claims 1-4, 6-8, and 10-13 are pending, claims 12-13 have been withdrawn from consideration, and claims 1-4, 6-8, and 10-11 stand as rejected by the Patent Office. In the present Response, claims 1 and 2 have been amended, claims 3-11 have been cancelled without prejudice, and new claims 14-19 have been added to better define that which the Applicant regards as his invention. Support for the amendments made and the new claims added can be found in FIGS. 1b, 2, 3b, and 5a-e, paragraphs 24-29 of the specification, and in the claims as originally filed. No new matter has been added. The Applicant respectfully requests reconsideration of the claims in light of the amendments, additions, and remarks made herein.

35 U.S.C. §103(a)

On pages 2-3 of the Office Action of February 23, 2007, the Patent Office states that claims 1-3, 6-7, 10 and 11 are rejected under 35 U.S.C. §103(a) as being unpatentable over Smith (U.S. Pat. No. 6,761,702) in view of Staid *et al.* (U.S. Pat. App. No. 2006/0264808). On page 3 of the Office Action, the Patent Office states that claims 4 and 8 are rejected under 35 U.S.C. §103(a) as being unpatentable over Smith in view of Staid, and further in view of Hawks (U.S. Pat. No. 4,943,285). For at least the reasons stated below, the amended claims and newly added claims are believed to define patentably over the § 103 references cited by the Patent Office and over the prior art in general.

MPEP 2142 provides that to establish a *prima facie* case of obviousness, three basic criteria must be met: (i) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings; (ii) there must be a reasonable expectation of success; and (iii) the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and must not be based on the Applicant's disclosure. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). The Applicant argues

that the amended claims, as well as the new claims, do not permit a finding of *prima facie* obviousness in the present application because the cited art does not teach nor suggest all the claim limitations of the Applicant's claimed invention, and/or there is no reasonable expectation of success in combining the teachings of the cited references.

The Applicant argues that Smith, Staid *et al.*, and Hawks do not, either individually or in combination, teach nor suggest all of the Applicant's claim limitations as required by MPEP 2142 for a finding of obviousness. Regarding Smith, the Applicant's claimed device (i.e., claims 1 and 16) provides a "housing that includes (i) a first chamber formed therein, wherein the first chamber is formed integrally with the housing and defines a first interior passage running partially lengthwise therethrough, and wherein the first chamber is adapted to receive a volume of pressurized fluid directed into the housing; (ii) a second chamber formed therein, wherein the second chamber is formed integrally with the housing and defines a second interior passage running lengthwise therethrough, and wherein the second chamber is adapted to receive a volume of fluid mixed with fecal matter exiting the housing; and (iii) a dividing wall formed between the first and second chambers, wherein the dividing wall is formed from the same material as the substantially cylindrical housing and is integral therewith, and wherein the dividing wall completely separates the first chamber from the second chamber for preventing mixing of the pressurized fluid entering the housing and the fluid and fecal matter exiting the housing". As argued previously, Smith does not teach a device that includes two separate chambers formed within a housing, wherein the separate chambers are defined by the housing itself and divided by a portion of the housing itself. Smith specifically states in Column 3, lines 56-60 that *"a medical grade PVC hose 26 ... is inserted through the seal 28 to extend through the tubular body 10 and the opening 16 into the colon of the patient."* Thus, there is only one chamber formed in the housing of Smith's device, and a length of hose (see Smith, Fig. 3), must be inserted into the tubular body (10) to introduce irrigation fluid into the colon of a patient. Clearly, the device taught by Smith does not include the limitation of a housing that has two separate and distinct chambers defined by the material of the housing itself. Smith requires two completely separate devices to create different chambers, whereas the Applicant's device requires only one device to create separate and distinct chambers.

Regarding Staid *et al.*, the Applicant's claimed device (i.e., claims 1 and 16) provides "a nozzle at one end of the housing, wherein the nozzle further includes: a plurality of forward-facing trapezoidal outlets formed circumferentially around the anterior portion thereof; an inlet formed in the posterior portion thereof, wherein the inlet is in fluid communication with both the first chamber and the plurality of trapezoidal outlets; and an effluent channel formed therethrough, wherein the effluent channel is in fluid communication with the second chamber formed in the housing." The device taught by Staid *et al.* does not include a plurality of outlets (only a single, backwards-facing outlet is shown in FIG. 5D), nor does the nozzle taught by Staid *et al.* include an effluent channel such as that claimed by the Applicant. Furthermore, the device taught by Staid *et al.* does not utilize a plurality of fluid outlets to create a high-pressure vortex that would be effective for removing impacted fecal matter from a subject's colon and, in fact, the device of Staid *et al.* is entirely inadequate and unsuitable for such a purpose. Thus, there is no reasonable expectation that a combination of Smith and Staid *et al.* would result in a device that would successfully function in the same manner as the Applicant's claimed device.

Regarding Hawks, the Applicant's claimed device (e.g., claim 2) provides "a removable insertion rod for facilitating insertion of the colon hydrotherapy device into a subject, wherein the second chamber further includes a ridge formed lengthwise therein, and wherein the shape of the front portion of the insertion rod corresponds to the shape of the ridge formed in the second chamber for stabilizing the insertion rod therein". The device taught by Hawks clearly does not include such a "keyed" design; rather the tip of Hawks' device is basically featureless with regard to the internal geometry of the claimed speculum (see FIG. 3 of Hawks).

As illustrated and emphasized by the remarks made herein, amended and new independent claims 1 and 16 respectively, and their corresponding dependent claims 2, 14-15, and 17-19 include multiple claim limitations that are not taught by the references cited by the Patent Office in the present application. Thus, because the cited references do not teach all of the claim limitations and there is no reasonable expectation of success, both of which are required by MPEP 2142, rejection of these claims under §103 is improper and should be withdrawn.

Conclusion

In light of the amendments made to the claims, the new claims added, and the arguments presented above, the Applicant asserts that the pending claims are not obvious in view of the cited references and that these claims define patentably over the art cited by the Patent Office and over the prior art, in general. For at least the reasons set forth herein, this application is believed to be in condition for allowance and favorable reconsideration is respectfully requested.

Respectfully submitted,

Date: July 16, 2007

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